



Kaiser Foundation Health Plan
Program Offices

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Submitted via email to sgillespie@ohi.ca.gov

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Re: HIE Demonstration Project – Notice of Revised Regulations

We appreciate the opportunity to offer the following comments on the revised proposed HIE Demonstration Project regulations (“Revised Regulations”). Kaiser Permanente recognizes and supports many of the changes the California Office of Health Information Integrity (“CalOHII”) has incorporated based on comments received in response to draft regulations issued March 1, 2011.

We support the additional clarification about the applicability of these Revised Regulations and the improvement related to incorporating/harmonizing Federal law. However, we have some remaining concerns, in particular, about the proposed requirements regarding patient consent for health information exchange (“HIE”).

Care coordination and improved quality are central goals of HIE and we continue to oppose any restrictions on the use and disclosure of health information that could threaten patient safety, or any consent mechanism that creates barriers for providers who need immediate and effective access to critical information for treatment purposes. Any privacy and security guidelines imposed on Demonstration Projects, or on HIE in general, should be consistent with what consumers expect from their health care providers and should not insert obstacles into the trust relationship and well-established practices of providers and their patients.

As we stated in our earlier comments, HIE demonstration projects should be structured to promote and evaluate different, reasonable consent models (e.g., variants of opt-in and opt-out, as considered during the Privacy and Security Advisory Board (“CalPSAB”) stakeholder workgroup process).

Kaiser Permanente addresses these issues based on our extensive experience with regional and Federal HIE models. Being in the forefront of electronic health record (“EHR”) and HIE

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technologies, Kaiser Permanente¹ is strongly committed to facilitating the development of health IT interoperability in order to enhance patient care and improve the health of the communities we serve.

Below we provide a summary of our principal concerns with the Revised Regulations in the following areas: scope of the regulation, definitions, patient consent, HIE permitted purposes, security and waivers. To address these concerns, we also suggest specific changes to the language of various provisions of the Revised Regulations in *Attachment A* to this letter.

Informing Requirements; Affirmative Consent [126055]

Kaiser Permanente believes that the premises for the consent requirement, as described in the *Statement of Reasons*, are fundamentally wrong. To our knowledge, PSAB never reached “a consensus in fall 2010 for an opt-in policy.”² Comments submitted by provider groups demonstrate consistent concerns that an opt-in approach would be contrary to existing practice and would erect a barrier to HIE adoption. Plus, some prominent consumer groups also opposed opt-in for similar reasons.³

We also disagree with CalOHII’s claim that there is no comprehensive rule to address privacy and security of PHI. California law has a comprehensive policy and rules that govern when patient consent is required for disclosure of PHI, and those rules have operated effectively, including for HIE projects already operating in the State.

As noted, HIE Demonstration Projects should permit and foster different approaches, not dictate a single approach as the default, especially if that approach diverges from existing law.

While we share concerns about overly permissive secondary uses of data, the “great concern” about secondary uses and disclosures of individual health information (“IHI”) via independent directed exchanges⁴ may be misplaced and unwarranted, given the narrow scope of these exchanges; similar exchanges have occurred for decades now (e.g., via fax), without any

¹ The Kaiser Permanente Medical Care Program is the largest private integrated healthcare delivery system in California. It comprises: Kaiser Foundation Health Plan, Inc., the largest not-for-profit health plan; the nonprofit Kaiser Foundation Hospitals and their subsidiaries; and the Permanente Medical Groups, independent physician group practices that contract with the health plan to meet the health needs of Kaiser Permanente’s approximately 6.5 million members in California. Most pharmacy, diagnostic, and laboratory services are performed within Kaiser Permanente. As part of its commitment to the highest quality care, Kaiser Permanente has made a significant investment in developing its secure Electronic Health Record (“EHR”) system, KP HealthConnect®, to support the delivery of care to its members and to enhance communications among the medical professionals who serve them.

² See *Statement of Reasons*, pg. 17.

³ See Consumers Union and Center for Democracy & Technology comments

⁴ See *Statement of Reasons*, pg. 24. We acknowledge the difficulties in assuring legitimate secondary use outside the narrow realm of independent directed exchange. For instance, we recommend considering reasonable future limitations on disclosures to non-public registries, with appropriate mechanisms for ensuring such registries are reliable stewards of their data and do not engage in unauthorized re-use and/or re-sale of IHI.

evidence of systemic violations of the Confidentiality of Medical Information Act (“CMIA”)⁵ by providers. In fact, electronic transmissions may allow for greater oversight of privacy and security within provider systems.

We recommend that CalOHII maintain a neutral approach, permitting opt-out in the demonstration projects, rather than fostering and perpetuating an automatic bias against opt-out. In the absence of strong evidence that there are substantial risks in current practices that require remediation, it would be more appropriate if these regulations adopted existing law as the baseline, while permitting different approaches to be tested, rather than overturning the current regulatory approach to patient consent for treatment disclosures.

We also recommend that “Informing” requirements be addressed in an entity’s Notice of Privacy Practices (“NPP”) and not require a separate, new document.

We strongly recommend that requirements for HIE disclosures in emergencies should not go beyond existing law that ensures providers’ rapid access to information that can be critical to patient safety.

Permitted Purposes [126050]

Kaiser Permanente supports the new subsection (b), which clarifies that IHI received through health information exchange may be used or disclosed as permitted by existing law and the recipient’s NPP. We also support including HIPAA-mandated transactions sets in the list of permitted purposes.

Definitions [126020]

Kaiser Permanente recommends revisions to the following definitions:

Affiliated Entity

The definition of “affiliated entity” is not broad enough to cover organizational arrangements that embody the affiliation approach, but do not meet the strict definition included in the revised proposed regulations. We recommend incorporating the concept of an organized health care arrangement (“OHCA”), as defined under HIPAA. Alternatively, the proposed regulations could cover this in the “HIO” and “Independent Directed Exchange” definitions. See *Attachment A*.

We also believe that defining the term “unaffiliated organization” would tighten other internal references.

Authorization

We suggest a clearer, more concise definition of “authorization.” We recommend deleting the first sentence and simplifying the definition to reflect current law. See *Attachment A*.

⁵ Cal. Health&Safety Code Section 56.10 *et seq.*

CMIA Provider

Distinguishing HIPAA-defined providers and “CMIA providers” will create confusion about which entities may disclose IHI under these proposed regulations.⁶ Limiting permissive disclosure by applying the narrower definition of a provider of health care under CMIA actually results in more restrictions than CMIA currently imposes on disclosures. For instance, CMIA permits health service plans to disclose medical information without authorization in various circumstances, while these regulations would not permit such disclosures through an HIO unless authorized. We are also concerned that restricting disclosures of IHI in emergent situations to CMIA providers may have negative consequences for patient health and safety.

An adequate justification has not been shown that a more restrictive definition of provider is necessary for “laying a foundation” for the use of IHI disclosed through an HIO or independent directed exchange of health information.

Sensitive Health Information

The use of the term “legally established” should be deleted because it is ambiguous, lacks accepted legal meaning and blurs rather than illuminates the term.

Security Section [126070]

While we support flexibility to allow Participants to develop system security policies and practices that can incorporate organizational and/or system characteristics, the requirements imposed in this section are overly vague. We recommend specific changes to the language to clarify the interpretation of these requirements and ensure that the Revised Regulations set reasonable standards for security (*See Attachment A*).

Transparency [126040]

We believe that requiring participants to submit EHR vendor contracts to CalOHII is unreasonable. There is no reason CalOHII would need to see other parts of the contract not related to the HIE functionality. Such a requirement is overbroad, burdensome, sensitive, irrelevant, and would be a deterrent to participation. We recommend narrowing the requirement to include only the relevant parts of the contract (*See Attachment A*).

Effective Dates; Duration and Scope of Authority [126010 and 126090]

The interaction of these provisions with respect to the reach and duration of CalOHII’s authority and the Demonstration Project regulations could be problematic. We recommend an automatic repeal date in addition to the declaration, with the earlier of the two being effective. We also recommend that the authority to audit be limited to what is directly relevant to HIE (*See suggested changes to those sections in Attachment A*).

⁶ *See Statement of Reasons*, pg. 6.

Rights of Access – Personal Representatives

Under both California law and HIPAA, an individual (i.e., the person who is the subject of the medical information) has certain rights of access. The personal representative stands in the shoes of the individual, but only up to a point. Certain circumstances will impact the personal representative's rights of access under law.⁷

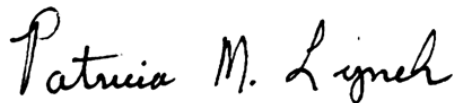
We are concerned that these Revised Regulations muddy this distinction when they consistently refer to the individual and the personal representative as if they have identical rights of access and amendment. Because that is not always the case, we recommend that the Revised Regulations use the term "individual," and then separately address the question of personal representatives and their access rights.

See our additional clarifications made in the redlined version enclosed as *Attachment A*.

Conclusion

We appreciate your willingness to consider our comments as you revised the proposed regulations. Please feel free to contact Lori Potter at 510-271-6621 (email Lori.Potter@kp.org) with any questions or concerns.

Sincerely,



Patricia M. Lynch
Vice President
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Encl: *Attachment A*

⁷ For example, parents have a right to access health information of unemancipated minors, when the information relates to care for which the minor may not lawfully consent. A provider may nonetheless deny access to the parent or other person in *loco parentis* if the provider determines in good faith that such access would have a detrimental effect on the provider's professional relationship with the minor or on the minor's physical safety or psychological well-being. See Cal Health & Safety Code 123115(a)(2). In cases involving adults, specifically when issues of neglect, domestic violence, or abusive conduct are raised in connection with the personal representative of an elder or dependent adult, the law provides the ability to deny the personal representative access and not treat him/her as the individual's stand-in. See 45 CFR 164.502(g)(5) addressing abuse, neglect and endangerment situations.